K011118

JUL 2 0 2001

510 (k) Summary

Device Name:
Normed Extremity Titanium Hand and Small Fragment System

Device Identification:
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Class II

Product Code:
87 HRS (21 CFR – 888.3030)

The Normed Extremity Titanium Hand and Small Fragment System consists of a series of plates in varying configurations (including, but not limited to, straight, curved, "T", "Y", zigzag, "L" ladder, and panel) and varying lengths which are attached to the bone using screw fixation. These plates are attached to bone using 1.2-2.7 mm diameter titanium self-tapping screws; screw diameter is depending upon plate thickness. The screws will be available in both standard and lag design with cross and center drive head feature.

The Normed Extremity Titanium Hand and Small Fragment System intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, toes and craniomaxillofacial skeleton. The system can be used in both adult and pediatric patients.

The substantial equivalence of these devices is based on equivalence in intended use, design, materials and operating principals to several legally marketed devices including the Lorenz Small Fragment System and Howmedica Profyle Titanium Hand and Small Fragment.

Official Contact Person:
Albert Enayati
President
Osteomedics Inc.
809 Carter Lane
Paramus, NJ 07652
Tel: (201) 444-7306
Fax: (201) 444-7395
E-mail: osteomedics@aol.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Mr. Albert Enayati
President
Osteomedics, Incorporated
809 Carter Lane
Paramus, New Jersey 07672

Re: K011118
Trade/Device Name: Normed Extremity Titanium Hand and Small Fragment System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS
Dated: July 10, 2001
Received: July 18, 2001

Dear Mr. Evayati:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does nct affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General
Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510 (k) Number (if known): K011118

Device Name: Normed Extremity Titanium Hand and Small Fragment System

Indications for use:

The Normed Extremity Titanium Hand and Small Fragment System intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use X OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011118

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